MAR 1 4 2001

K010687

510(k) Summary
Bionc Implants Inc.´s
BioSorbFX and BioSorbPDX Mesh

Submitter´s Name, Address, Telephone Number, and Contact Person

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Date prepared: February 26th, 2001

Name of the Device: BioSorbFX and BioSorbPDX Mesh, Bioabsorbable craniofacial bone plate

Common or Usual Name:
Bioabsorbable craniofacial bone plate

Classification Name: Bioabsorbable craniofacial bone plate (Product Code 76 JEY), class II

Predicate Devices:
1. Bionx Implants, Inc. BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System ("BioSorbFX™ 1.5/2.0 System") (K982139)
2. Bionx Implants, Inc. BioSorbPDX System (K000836)
3. Bionx Implants, Inc. ThermoFX Mesh (K003757)

Intended Use

BioSorbFX and BioSorbPDX Meshes are intended for use with fixation fasteners, i.e. screws and tacks in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton.

BioSorbFX and BioSorbPDX Meshes are not intended for use in and is contraindicated for: 1) the mandible; 2) full load bearing procedures; 3) areas with active infection; or 4) patient conditions, including blood supply limitations, insufficient quantity or quality of bone or latent infections.

Device Description and Principles of Operation

BioSorbFX and BioSorbPDX Meshes, bioabsorbable craniofacial bone plates are provided with two thickness, 0.6 and 0.8mm and with several dimensions 26 x 26mm, 51 x 51mm, 51 x 76 mm and 76 x 76mm. Design of the mesh plates is identical, only difference is raw material. BioSorbFX Mesh is intended for use with BioSorbFX 1.5/2.0 System fixation fasteners, i.e. screws and tacks made of poly-L/DL-lactide copolymer and BioSorbPDX Mesh is intended for use with BioSorbPDX System fixation fasteners, i.e. screws and tacks made of polylactideglycolide raw material.

The used instrumentation is chosen according to the selected fixation fastener.

Technological Characteristics and Substantial Equivalence

As noted above, BioSorbFX and BioSorbPDX Meshes are provided with two alternative raw materials, made of polylactide-glycolide copolymer and poly-L/DL-lactide copolymer. These raw materials are the very same than used in the previously cleared BioSorbPDX System (K000836) and BioSorbFX™ 1.5/2.0 System (K982139), BioSorbFX and BioSorbPDX Tack (K003756) and ThermoFX Mesh (K003757).

Bionx Implants Inc. BioSorbFX and BioSorbPDX Meshes and bioabsorbable craniofacial bone plates included in BioSorbPDX System (K000836) and BioSorbFX™ 1.5/2.0 Bioabsorbable Fixation System (K982139) have the same intended use and principles of operation and very similar design characteristics. The minor technical differences between BioSorbFX and BioSorbPDX Meshes and the predicate devices do not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2001

Bionx Implants, Incorporated
C/O Ms. Tuija Annala
Quality Manager
Bionx Implants, Limited
Hermiankatu 6-8 L
Tampere,
FINLAND

Re: K010687
Trade Name: BioSorbFX and BioSorbPDX Mesh
Regulatory Class: II
Product Code: JEY
Dated: February 26, 2001
Received: March 8, 2001

Dear Ms. Annala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K010687

Device Name: BioSorbFX and BioSorbPDX Mesh

Bioabsorbable craniofacial bone plate

Indications for Use:

BioSorbFX and BioSorbPDX Meshes are intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton.

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(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010687